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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/419,611	10/18/1999	HIROSHI IZUI	0010-1045-0	1525

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EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/419,611	IZUI ET AL.	
	Examiner	Art Unit	
	Christian L. Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *49-52* is/are allowed.

6)☒ Claim(s) *34-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 October 1999* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. New claims 34-52 are under consideration in this Office Action.

2. Previous rejections of claims 1, 2, 6-14, 16, and 28-33 are moot in view of applicants' cancellation of the claims in the amendment dated 03/20/2006 and have been withdrawn. New rejections and new grounds of rejection are presented for new claims 34-52.

Claim Rejections - 35 U.S.C. § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 38-45 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

The claims, as written, do not sufficiently distinguish over microorganisms as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of the phrase "An isolated microorganism". See MPEP 2105.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 34-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The examiner acknowledges that in the Capon decision, which is cited in applicants' amendment dated 03/20/2006, the Federal Circuit held that there is no rule that the specification must provide a specific sequence if that sequence is known in the art. However, the new claims do not meet the written description requirement for the reasons stated below.

The claims are genus claims that are directed toward a genus of microorganisms belonging to *Enterobacter, Pantoea, Klebsiella, Erwinia,* and *Serattia* which are transformed with a polynucleotide of any nucleotide sequence encoding a citrate synthase obtained from *Corynebacterium glutamicum* or *Brevibacterium lactofermentum* and a method for producing L-glutamic acid using said microorganisms. The claimed genus is widely variant in their physiological characteristics, functions, and/or structures. According to MPEP §2163 for claims drawn to a genus the written description requirement may be met through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, where a representative number of species means that the species which are adequately described are representative of the entire genus.

However, the specification only discloses bacterial strain AJ13355/pMWCB which is an *Enterobacter agglomerans* transformed with a polynucleotide from *Brevibacterium lactofermentum* encoding citrate synthase and bacterial strain AJ13399/pMWCB which is an *Klebsiella planticola* transformed with a polynucleotide from *Brevibacterium lactofermentum* encoding citrate synthase, where said polynucleotide from *Brevibacterium lactofermentum* encoding citrate synthase is obtained by PCR using primers of SEQ ID NO: 1 and SEQ ID NO: 2. The specification fails to disclose any additional species of the genus which are representative of the claimed genus of microorganisms. As such, the disclosure of bacterial strains AJ13355/pMWCB and AJ13399/pMWCB is insufficient to be representative of the attributes and features of all species encompassed by the claimed genus.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definitions, such as the structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), quoting *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe the genus of genetic materials, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g. structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed

correlation between function and structure, or a combination of these. Therefore, the instant claims are not adequately described.

7. Claims 34-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass microorganisms belonging to *Enterobacter, Pantoea, Klebsiella, Erwinia,* and *Serattia* which are transformed with a polynucleotide of any nucleotide sequence encoding a citrate synthase obtained from *Corynebacterium glutamicum* or *Brevibacterium lactofermentum* and a method for producing L-glutamic acid using said microorganisms. Although the specification discloses bacterial strains AJ13355/pMWCB and AJ13399/pMWCB, the process disclosed in the specification to make them does not appear to be repeatable. The nucleotide sequences of the plasmid vectors used to make the strains are not fully disclosed, nor have all the nucleotide sequences required for their construction been shown to be biblically known and freely available. The specification does not disclose a repeatable process to obtain the plasmids and it is not apparent if the nucleotide sequences are readily available to the public. It is not apparent if the source materials to make the bacterial strains are both known and readily available to the public.

Thus, an undue amount of trial and error experimentation must be preformed where such experimentation involves searching and screening a vast number of microorganisms selected from the group consisting of *Enterobacter, Pantoea, Klebsiella, Erwinia,* and *Serattia;* transforming the microorganism with any polynucleotide from *Corynebacterium glutamicum* or *Brevibacterium lactofermentum* encoding any citrate synthase; and determining whether the transformed microorganism can overproduce L-glutamic acid compared to an untransformed microorganism. This trial and error experimentation is well outside the scope of routine experimentation. General teaching regarding screening and searching for these microorganisms that overproduce L-glutamic acid compared to an untransformed microorganism is not guidance for making the claimed invention.

An enabling deposit of bacterial strains AJ13355/pMWCB and AJ13399/pMWCB may overcome the rejection. If the deposit is made under the terms of the Budapest Treaty, then an

affidavit or declaration by the applicant, or a statement by an attorney of record over his/her signature and registration number, stating that the specific microorganism has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809 and MPEP 2402-2411.05, the applicant may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his/her signature and registration number, showing that:

(1) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(2) all restriction upon availability to the public will be irrevocably removed upon granting of the patent;

(3) the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

(4) the deposit will be replaced if it should ever become inviable.

Conclusion

8. Claims 49-52 are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272 0929. The examiner can normally be reached Monday-Friday between 9:00AM 5:00PM. If attempts to

reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272 0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866 217 9197 (toll free).

CLF

TEKCHAND SAIDHA
PRIMARY EXAMINER